DECLARATION OF JAMES E DVORSKY UNDER 37 CFR 1.132

I, James E Dvorsky, of 3567 Braidwood Drive, Hilliard, Ohio 43026, United States of America, hereby declare the following:

- I am Product Development Leader in Medical Device Solutions of Battelle Memorial Institute, 505 King Avenue, Columbus, OH 43201 since 1982
- I have BSc and MSc in Electrical Engineering from Carnegie Mellon University
- I am the inventor or co-inventor of over 35 U.S. and international patents and nearly as many patents pending. The subject matter of most of these patents is electrohydrodynamic (EHD) aerosol and fiber formation, methods of producing fine droplets or fibers and devices that implement these methods.
- A comprehensive listing of my education, training, and accomplishments is set forth in my *Curriculum Vitae* attached to and incorporated in this Declaration.
- I have read and understand the disclosure of US 2006/0115894 A1 (Wan) as well as the claims set forth in the Preliminary Amendment dated 11/12/2009;
- I have read and understand the disclosure and claims of US 6,095,148 (Shastri et al.)
- I have read the portion of the Office Action dated May 12, 2009 wherein Examiner describes the teachings of the Shastri reference and I have read the portion of the Advisory Action 10/27/2009 where the Shastri reference is discussed;
- It is my opinion, based on my training and on my experience of over 12 years working in the area of electrohydrodynamic aerosolization of liquids that one skilled in this art would not consider the polymers used by Wan in the methods claimed in the Preliminary Amendment to be the same as, or equivalent to the electrically conductive polymers used by Shastri.
- The Shastri reference describes "electrically conductive" polymers as a "conjugated polymer which can be reversibly oxidized and reduced"; the polymers used by Wan in her invention are not capable of being "reversibly oxidized and reduced" and are thus, not electrically conductive.

- The Shastri reference describes "other polymeric materials which can be blended or coated with the conducting polymers" presumably because the "other polymeric materials" do not have the desired electrical properties to support the claims by Shastri, et al.

- The Shastri reference lists several examples of "other polymeric materials" that include poly(esters), poly (methacrylate), poly (ethylene) and poly (lactic acid).

- The materials highlighted in the Wan specification are among the list of "other polymeric materials" of the Shastri reference. Namely, Eudragit is "a co-polymer based on (2-dimethylaminoethyl) methacrylate, butyl methacrylate and methyl methacrylate. Polycaprolactone is biodegradable polyester; Polymethylmethacrylate (PMMA) is another member of the methacrylate family of chemistries, and polylactide is another name for polylactic acid.

- As illustrated by e.g., Fig. 2 and Fig. 7 of the Wan specification, the liquid solution containing a biologically compatible polymer is subjected to an electric field in order to overcome the surface tension of the liquid and to produce fibres at the nozzle tip; there is a surface charge on the polymer fibres as they are discharged from the nozzle tip.

- It is my opinion as one skilled in this art, that skilled artisans would understand that the fact that a polymer fibre is capable of carrying a surface charge does not mean the polymer fibers are electrically conductive; in fact, all dielectric materials are able to carry surface charge but by their nature are not electrically conductive and are used as electrical insulators.

- I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Date: November 10, 2009 By: _____

Name: James E Dvorsky.

Product Development Leader
Medical Device Solutions

Education

M.S. (Honors), Electrical Engineering, Carnegie-Mellon University
B.S. (Honors), Electrical Engineering, Carnegie-Mellon University

Qualifications

Mr. Dvorsky has more than 25 years of experience as a product development engineer. His experience and expertise are broad, and he frequently contributes to programs as chief scientist, chief technologist, senior design engineer, project leader, lead research investigator, or mentor. Mr. Dvorsky is noted for his problem solving skills and is often invited to develop innovative concepts to address complex issues. In a number of development efforts, he has carried early concepts and integrated cutting edge technologies through design and development and into production.

Mr. Dvorsky's interests focus on applying electrical processes to "real world" requirements and his engineering skills include electrical/electronic equipment development—particularly those including electromagnetic/electrostatic designs, analog circuitry, systems integration, and electronic packaging. He has developed a number of electromechanical devices and sensor systems, and he has designed systems for compliance with electrical safety and electromagnetic compatibility requirements as stipulated in domestic and international standards for medical electrical equipment.

Honored as a Battelle Distinguished Inventor and Inventor of the Year, Mr. Dvorsky is a prolific inventor and has worked closely with patent attorneys to position intellectual property. He has worked closely with Battelle's corporate management to evaluate licensing and acquisition opportunities, and he has provided technical leadership to Battelle's Electric Field Effect Technology product platform since its inception. His responsibilities included overseeing an annual budget of over one million dollars, developing and executing a research agenda for the platform, and overseeing operations of a small, international biotechnology company.

Relevant Experience

Product Safety and Electromagnetic Compatibility. Mr. Dvorsky has worked with product development teams, customers and nationally recognized testing laboratories (NRTLs) to ensure product safety and electromagnetic compatibility (EMC) of medical, laboratory, and commercial products per international and domestic standards. His expertise of UL/EN/IEC60601, EN61010, IEC6950, IEC61000 and other accepted standards and design methodologies has been instrumental to the efficient implementation of critical product safety features throughout the design and development process. Mr. Dvorsky routinely shepherds newly developed devices through preliminary and final qualification testing.

Electric Field Effect Technology (EFET) Product Platform. From Battelle's earliest interests in electric field aerosol generation, Mr. Dvorsky has worked with Battelle attorneys and management to evaluate both the licensing of EFET from Electrosols, Ltd. to Battelle's purchase of the company. After the acquisition, Battelle formed the EFET Product Platform, and Mr. Dvorsky has led both the platform direction and the operations of Electrosols in Oxford, England. He developed the research agenda and works with commercialization managers and customers from several business groups engaged in or considering EFET to solve their challenging problems. Mr. Dvorsky is responsible for the technical leadership of EFET platform activities and those of Battelle's project teams engaged in the development of agrochemical spraying, quick dissolving dosage forms, wound care products, spray coating, and pulmonary drug delivery. He has also been responsible for the oversight of the large intellectual property portfolio, including its positioning, maintenance and growth, and is regularly engaged with Battelle's patent attorneys and several firms providing outside counsel.

Electrohydrodynamic (EHD) Sprayers. Mr. Dvorsky has served as the Chief Scientist to Battelle's program to develop a family of pulmonary drug delivery devices using EHD as the aerosolizing process. He has been leader of the nozzle development team, which has been responsible for generating and exploring innovative sprayer designs, studying the principles of EHD spraying to exploit its traits in new devices, and supporting two device development efforts in the implementation of the technology. He has been granted patents for several devices that utilize unique architectures for maximizing mass transfer efficiency of the aerosol to a patient.

Independent Consultant. Throughout much of his career, Mr. Dvorsky has been sought after to provide independent reviews of designs prior to manufacturing or to troubleshoot products already on the market. He has consulted with Liebert (multi-kW UPS), Insinkerator (high temperature water purifier), Ridge Tool (various tools), Stereotaxis (magnetic field shielding), Thermodisc (circuit protectors), US Navy (10kW electromagnet), Caterpillar, Emerson Motors, Hospira, Abbott Laboratories and many others.

Pulmonary Drug Delivery Devices. Mr. Dvorsky has been the Lead Electronics Designer for the bench top drug deliver device. His role included the development and implementation of signal processing and interface electronics, as well as their packaging within the system. He also served as a Technical Advisor to the team developing a hand-held delivery device. For the overall program, he was the Safety Compliance Specialist and has worked closely with Underwriters Laboratories to ensure that both drug delivery devices are designed to be compliant with regulations UL and IEC 60601 for medical electrical equipment. He has overseen device testing, including that for electromagnetic compatibility (EMC) and ozone generation levels as dictated by the Food and Drug Administration (FDA).

Gamma Detection System. In a major program to develop a gamma detection system, he served as the program's Chief Scientist and as Chief Technologist for probe development. The system was a surgical device consisting of a miniature hand-held probe with an electrical umbilical and an electronic console. The probe contained a cadmium-zinc-telluride crystal and sensitive electronic circuitry for converting detected gamma rays into electrical signal pulses. In use, the surgeon can locate radioactively tagged cancerous tissue or trace the lymphatic system and locate a primary drainage site of cancerous cells, the so-called

"sentinel node." He ushered this product through EMC and full safety compliance testing, and customer reactions have been quite favorable. The product itself has been very success in the market and has become the standard of care.

Electric Toothbrush. For a next generation electric toothbrush, Mr. Dvorsky designed and implemented a small, high-efficiency, brushless motor. It utilizes high energy density SmCo permanent magnets and operates from less than 2.5 VDC. Directly coupled to the brush head, the motor oscillates the bristles at rate of 30,000 strokes per minute and is designed with inductively-coupled feedback to maintain its amplitude under a variety of loads. This device has been successfully marketed, and a U.S. patent was granted.

Dual Motion Actuator. By analyzing the electromagnetic characteristics of permanent magnet DC motors, Mr. Dvorsky developed a unique actuator for electrically operating the windows and door locks in automobiles, as well as other applications. A breadboard unit was fabricated that demonstrated both traditional rotary motion for window regulation, as well as translational motion, typically accredited to solenoids, for lock actuation. The single motor was designed to reduce the manufacturing cost and assembly requirements of associated with conventional motors. A U.S. patent and an R&D 100 Award were granted for this concept.

Sensors and Signal Processing. Mr. Dvorsky has designed and demonstrated several non-contact sensors. He developed a magnetically coupled position detector to indicate the location of objects in a high-pressure hydraulic line. The sensor employs field generating and receiving coils and associated signal processing electronic circuitry. A magnetoresistive displacement sensor was designed for measuring gap thickness in surgical staplers. The instruments, including electronic circuitry housed in the tool, were subject to intense radiation exposure (up to 10 Mrad) during sterilization. Mr. Dvorsky was Chief Technologist to a pair of programs whose missions were to effectively place and detect the location of magnetically tipped enteral feeding tubes inserted to a patient. He has effectively employed a number of custom-designed non-contact sensors for detecting displacement or force in rugged operating environments.

Mr. Dvorsky has worked extensively with piezoelectric polymer film in the development of various sensors. By using the material for measuring vibration, he developed transducers for monitoring the operating condition of rotating machining and for measuring boiling intensity in commercial cooking. For the paper manufacturing industry, he developed a prototype nip pressure sensor, as well as a series of patented sensors for measuring the surface topology of tissue paper, textiles, and other delicate materials.

Major Government Program. Mr. Dvorsky was Task Leader and Electrical Systems Principal Investigator on a continuing program for a military client. He was responsible for the design, development, fabrication, and field installation of several pieces of electronic control and signal processing equipment. He coordinated and directed the activities of his development team members, as well as maintained client liaison, project schedule and budget, documentation, and quality control and assurance. As a result of his efforts, Mr. Dvorsky has successfully installed and maintained over 270 assemblies, enclosed in 12 packages, which represents over 33 circuit board designs, for this customer alone.

Professional Recognition and Affiliations

Battelle Memorial Institute recognized James Dvorsky as a Distinguished Inventor in March 2003 and Inventor of the Year in 2006.

Mr. Dvorsky was a recipient of the 2000 R&D 100 Award for the neo2000 Gamma Detection System™.

Mr. Dvorsky was also a recipient of the 1993 R&D 100 Award for the Dual-Motion Actuator, and subsequently named as one of fifty "R&D Stars to Watch" by *Industry Week* magazine.

Mr. Dvorsky is a Fortescue Fellow and a member of Eta Kappa Nu and Tau Beta Pi.

Publications

Dvorsky, J. E., "Dual-Motion Motor Can Reduce Cost, Weight, Complexity," *B-Tip Technology Spectrum*, No. 34, May 1992.

Dvorsky, J. E., "New Sensor Has A Soft Touch," *B-Tip Technology Spectrum*, No. 12, December 1989.

Rosen, R. D., and Dvorsky, J. E., "Portable Data Carrier Technology," Winter, 1988, *Data Processing and Communications Security*, Vol. 12, No. 1.

Dvorsky, J. E., "Non-Contact Coupling to Portable Data Carriers," 1987 Smart Card Applications and Technologies Conference, Atlantic City, New Jersey.

Dvorsky, J. E., Hoburg, J. F., and Penny, G. W., "Correlations of Single-Stage and Cascaded Two-Stage/Single-Stage Precipitation Efficiencies to Particle Resistivity," *IEEE Transactions on Industry Applications*, Volume IA-20, No. 1, Jan/Feb 1984, presented at the 1982 Industry Applications Society Annual Meeting, San Francisco, California.

Thesis: Correlation of Two-Stage Precipitator Blow-off Collection Efficiency to Particle Resistivity.

Patents

34. Dissociated Discharge EHD Sprayer with Electric Field Shield (US20080308095)
33. Dispensing Device and Method (US20070017505)
32. Process for Treating Non-human Animals (US2006179491)
31. Quick Dissolving Agrochemical and Animal Health Products (US2005019441)
30. Nozzle for Handheld Pulmonary Aerosol Delivery Device (US20040195403)
29. Aerosol Dispensing Device and Method (US20060180143)
28. Pulmonary Aerosol Delivery Device and Method (US20020153006)
27. Core Sampling Biopsy Device with Short Coupled MRI-Compatible Driver (US20060149163)
26. Pulmonary Aerosol Delivery Device and Method (US20050039738)
25. Spray Head for Electrohydrodynamic Spray Device and Electrohydrodynamic Sprayer System (US20060208112)
24. Diffractive Display (US20040017597)
23. Thermal Water Treatment (US20020050478)

22. Pulmonary Aerosol Delivery Device (US2050236501)
21. Electric Field Spraying of Surgically Implantable Components (US20050064168)
20. Highly-Aqueous, Non-Respirable Aerosols Containing Biologically-Active Ingredients, Methods of Making, and Device Therefor (US20080259519)
19. Diffractive Display (6,898,009)
18. Thermal Water Treatment (6,835,307)
17. Pulmonary Aerosol Delivery Device and Method (6,796,303)
16. Diffractive Display (6,621,607)
15. High Mass Transfer Electrosprayer (6,454,193)
14. Pulmonary Aerosol Delivery Device and Method (6,397,838)
13. Directionally Controlled Sprayer (6,302,331)
12. Detector Unit for Radiation Detecting Probe (D424,453)
11. Radiation Detecting Probe (D423,377)
10. Radiation Detecting Probe (D413,532)
9. Handle Unit for Radiation Detecting Probe (D390485)
8. Radiation Detecting Probe (D390481)
7. Detector Unit for Radiation Detecting Probe (D390480)
6. High Frequency Automatic Toothbrush (5,613,259)
5. Endoscopic Surgical Instrument with Electromagnetic Sensor (5,395,033)
4. Dual-Motion Apparatus (5,045,741)
3. Texture Softness Sensing (4,869,101)
2. Topography Sensor (4,811,594)
1. Active Tactile Sensor Apparatus and Method (4,634,917).